

Amendments to the Claims

1. (currently amended) A method of treating psychosis in a patient comprising administering a therapeutic amount of an antipsychotic a drug condensation aerosol to the patient by inhalation,

wherein the drug is selected from the group consisting of olanzapine, trifluoperazine, haloperidol, loxapine, risperidone, clozapine, quetiapine, promazine, thiothixene, chlorpromazine, droperidol, prochlorperazine and fluphenazine, and

wherein the condensation aerosol is formed by heating a thin layer containing the drug, on a solid support, to produce a vapor of the drug, and condensing the vapor to form a condensation aerosol characterized by less than 10% drug degradation products by weight, and having an MMAD of less than 5 microns. ~~3 μ m and less than 5% antipsychotic drug degradation products, to a patient by inhalation, upon activation by the patient of the formation of, and delivery of, the condensation aerosol.~~

2. (currently amended) The method ~~of~~ according to claim 1, wherein the condensation aerosol is characterized by an MMAD of less than 3 microns. ~~wherein said condensation aerosol is formed by~~

a. ~~volatilizing an antipsychotic drug under conditions effective to produce a heated vapor of the antipsychotic drug; and~~

b. ~~condensing the heated vapor of antipsychotic drug to form condensation aerosol particles.~~

3. (currently amended) The method according to claim 2 1, ~~wherein said administration results in a peak plasma drug concentration of said antipsychotic drug is reached~~ in less than 0.1 hours.

4. (cancelled)

5. (currently amended) The method according to claim 3 1, wherein the ~~administered~~ condensation aerosol is formed at a rate greater than 0.5 mg/second.

6. (original) The method according to claim 1, wherein at least 50% by weight of the condensation aerosol is amorphous in form.

7. (cancelled)

8. (cancelled)

9. (cancelled)

10. (cancelled)

11. (currently amended) The method according to claim 7 1, wherein said the therapeutic amount of a drug ~~olanzapine~~ condensation aerosol comprises between 0.2 mg and 20 mg of olanzapine delivered in a single inspiration. ~~has an inhalable aerosol mass density of between 0.2 mg/L and 20 mg/L when delivered.~~

12. (currently amended) The method according to claim 7 1, wherein said the therapeutic amount of a drug ~~trifluoperazine~~ condensation aerosol comprises between 0.2 mg and 10 mg of trifluoperazine delivered in a single inspiration. ~~has an inhalable aerosol mass density of between 0.2 mg/L and 10 mg/L when delivered.~~

13. (currently amended) The method according to claim 7 1, wherein said the therapeutic amount of a drug ~~haloperidol~~ condensation aerosol comprises between 0.2 mg and 10 mg of haloperidol delivered in a single inspiration. ~~has an inhalable aerosol mass density of between 0.2 mg/L and 10 mg/L when delivered.~~

14. (currently amended) The method according to claim 7 1, wherein said the therapeutic amount of a drug ~~loxapine~~ condensation aerosol comprises between 2 mg and 100 mg of loxapine delivered in a single inspiration. ~~has an inhalable aerosol mass density of between 2 mg/L and 100 mg/L when delivered.~~

15. (currently amended) The method according to claim 7 1, wherein said the therapeutic amount of a drug ~~risperidone~~ condensation aerosol comprises between 0.1 mg and 5 mg of risperidone delivered in a single inspiration. ~~has an inhalable aerosol mass density of between 0.1 mg/L and 5 mg/L when delivered.~~

16. (currently amended) The method according to claim 7 1, wherein said the therapeutic amount of a drug ~~clozapine~~ condensation aerosol comprises between 2 mg and 200 mg of clozapine

delivered in a single inspiration. ~~has an inhalable aerosol mass density of between 2 mg/L and 200 mg/L when delivered.~~

17. (currently amended) The method according to claim 7 1, wherein said the therapeutic amount of a drug quetiapine condensation aerosol comprises between 2 mg and 200 mg of quetiapine delivered in a single inspiration. ~~has an inhalable aerosol mass density of between 2 mg/L and 200 mg/L when delivered.~~

18. (currently amended) The method according to claim 7 1, wherein said the therapeutic amount of a drug promazine condensation aerosol comprises between 2 mg and 200 mg of promazine delivered in a single inspiration. ~~has an inhalable aerosol mass density of between 2 mg/L and 200 mg/L when delivered.~~

19. (currently amended) The method according to claim 7 1, wherein said the therapeutic amount of a drug thiothixene condensation aerosol comprises between 0.5 mg and 20 mg of thiothixene delivered in a single inspiration. ~~has an inhalable aerosol mass density of between 0.5 mg/L and 20 mg/L when delivered.~~

20. (currently amended) The method according to claim 7 1, wherein said the therapeutic amount of a drug chlorpromazine condensation aerosol comprises between 2 mg and 200 mg of chlorpromazine delivered in a single inspiration. ~~has an inhalable aerosol mass density of between 2 mg/L and 200 mg/L when delivered.~~

21. (currently amended) The method according to claim 7 1, wherein said the therapeutic amount of a drug droperidol condensation aerosol comprises between 0.2 mg and 20 mg of droperidol delivered in a single inspiration. ~~has an inhalable aerosol mass density of between 0.2 mg/L and 20 mg/L when delivered.~~

22. (currently amended) The method according to claim 7 1, wherein said the therapeutic amount of a drug prochlorperazine condensation aerosol comprises between 0.5 mg and 20 mg of prochlorperazine delivered in a single inspiration. ~~has an inhalable aerosol mass density of between 0.5 mg/L and 20 mg/L when delivered.~~

23. (currently amended) The method according to claim 7 1, wherein ~~said~~ the therapeutic amount of a drug fluphenazine condensation aerosol comprises between 0.1 mg and 10 mg of fluphenazine delivered in a single inspiration. ~~has an inhalable aerosol mass density of between 0.1 mg/L and 10 mg/L when delivered.~~

24. (currently amended) A method of administering ~~an antipsychotic drug~~ a drug condensation aerosol to a patient ~~to achieve a peak plasma drug concentration rapidly, comprising administering to the patient by inhalation an aerosol of an antipsychotic drug having less than 5% antipsychotic by inhalation,~~

wherein the drug is selected from the group consisting of olanzapine, trifluoperazine, haloperidol, loxapine, risperidone, clozapine, quetiapine, promazine, thiothixene, chlorpromazine, droperidol, prochlorperazine and fluphenazine, and

wherein the drug condensation aerosol is formed by heating a thin layer containing the drug, on a solid support, to produce a vapor of the drug, and condensing the vapor to form a condensation aerosol characterized by less than 10% drug degradation products by weight, and an MMAD of less than 3 microns ~~5 microns.~~

~~wherein the peak plasma concentration of the antipsychotic drug is achieved in less than 0.1 hours.~~

25. (cancelled)

26. (currently amended) A kit for delivering a drug condensation aerosol comprising:

a) a. ~~a thin coating of an antipsychotic drug composition and layer~~ containing the drug, on a solid support, wherein the drug is selected from the group consisting of olanzapine, trifluoperazine, haloperidol, loxapine, risperidone, clozapine, quetiapine, promazine, thiothixene, chlorpromazine, droperidol, prochlorperazine and fluphenazine, and

b) b. a device for providing the condensation aerosol, wherein the condensation aerosol is formed by heating the thin layer to produce a vapor of the drug, and condensing the vapor to form a condensation aerosol characterized by less than 10% drug degradation products by weight, and an MMAD of less than 5 microns. ~~dispensing said thin coating as a condensation aerosol.~~

27. (cancelled)

28. (currently amended) The kit of according to claim 26, wherein the device ~~for dispensing said coating of an antipsychotic drug composition as an aerosol~~ comprises:

- (a) a a flow through enclosure containing the solid support,
- (b) ~~contained within the enclosure, a metal substrate with a foil-like surface and having a thin coating of an antipsychotic drug composition formed on the substrate surface,~~
- (c) b a power source that can be activated to heat the ~~substrate to a temperature effective to volatilize the antipsychotic drug composition contained in said coating~~ solid support, and
- (d) d ~~inlet and exit portals~~ at least one portal through which air can be drawn through said device by inhalation,

wherein ~~heating the substrate by~~ activation of the power source is effective to produce a vapor of the drug, and drawing air through the enclosure is effective to condense the vapor to form the condensation aerosol. ~~form an antipsychotic drug vapor containing less than 5% antipsychotic drug degradation products, and drawing air through said chamber is effective to condense the antipsychotic drug vapor to form aerosol particles wherein the aerosol has an MMAD of less than 3 microns.~~

29. (currently amended) The kit according to claim 28, wherein the heat for heating the ~~substrate~~ solid support is generated by an exothermic chemical reaction.

30. (currently amended) The kit according to claim 29, wherein said ~~the~~ exothermic chemical reaction is oxidation of combustible materials.

31. (currently amended) The kit according to claim 28, wherein the heat for heating the ~~substrate~~ solid support is generated by passage of current through an electrical resistance element.

32. (currently amended) The kit according to Claim 28, wherein ~~said substrate~~ the solid support has a surface area dimensioned to accommodate a therapeutic dose of the drug. ~~an antipsychotic drug composition in said coating.~~

33. (currently amended) The kit according to claim 26, ~~wherein a peak~~ wherein peak plasma drug concentration of antipsychotic drug is obtained is reached in less than 0.1 hours ~~after delivery of the condensation aerosol to the pulmonary system.~~

34. (currently amended) The kit of according to claim 26, further including instructions for use.

35. (new) The method according to claim 1, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 5 microns.

36. (new) The method according to claim 2, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 3 microns.

37. (new) The method according to claim 1, wherein the condensation aerosol comprises at least 80% drug by weight.

38. (new) The method according to claim 37, wherein the condensation aerosol comprises at least 95% drug by weight.

39. (new) The method according to claim 1, wherein the thin layer comprises at least 80% drug by weight.

40. (new) The method according to claim 39, wherein the thin layer comprises at least 95% drug by weight.

41. (new) The method according to claim 24, wherein the drug is olanzapine.

42. (new) The method according to claim 24, wherein the drug is trifluoperazine.

43. (new) The method according to claim 24, wherein the drug is haloperidol.

44. (new) The method according to claim 24, wherein the drug is loxapine.

45. (new) The method according to claim 24, wherein the drug is risperidone.

46. (new) The method according to claim 24, wherein the drug is clozapine.

47. (new) The method according to claim 24, wherein the drug is quetiapine.

48. (new) The method according to claim 24, wherein the drug is promazine.

49. (new) The method according to claim 24, wherein the drug is thiothixene.
50. (new) The method according to claim 24, wherein the drug is chlorpromazine.
51. (new) The method according to claim 24, wherein the drug is droperidol.
52. (new) The method according to claim 24, wherein the drug is prochlorperazine.
53. (new) The method according to claim 24, wherein the drug is fluphenazine.
54. (new) The kit according to claim 26, wherein the condensation aerosol is characterized by an MMAD of less than 3 microns.
55. (new) The kit according to claim 26, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 5 microns.
56. (new) The kit according to claim 54, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 3 microns.
57. (new) The kit according to claim 26, wherein the condensation aerosol comprises at least 80% drug by weight.
58. (new) The kit according to claim 57, wherein the condensation aerosol comprises at least 95% drug by weight.
59. (new) The kit according to claim 26, wherein the thin layer comprises at least 80% drug by weight.
60. (new) The kit according to claim 59, wherein the thin layer comprises at least 95% drug by weight.
61. (new) The kit according to claim 26, wherein the drug is olanzapine.

- 62. (new) The kit according to claim 26, wherein the drug is trifluoperazine.
- 63. (new) The kit according to claim 26, wherein the drug is haloperidol.
- 64. (new) The kit according to claim 26, wherein the drug is loxapine.
- 65. (new) The kit according to claim 26, wherein the drug is risperidone.
- 66. (new) The kit according to claim 26, wherein the drug is clozapine.
- 67. (new) The kit according to claim 26, wherein the drug is quetiapine.
- 68. (new) The kit according to claim 26, wherein the drug is promazine.
- 69. (new) The kit according to claim 26, wherein the drug is thiothixene.
- 70. (new) The kit according to claim 26, wherein the drug is chlorpromazine.
- 71. (new) The kit according to claim 26, wherein the drug is droperidol.
- 72. (new) The kit according to claim 26, wherein the drug is prochlorperazine.
- 73. (new) The kit according to claim 26, wherein the drug is fluphenazine.
- 74. (new) The kit according to claim 28, wherein the solid support has a surface to mass ratio of greater than 1 cm² per gram.
- 75. (new) The kit according to claim 28, wherein the solid support has a surface to volume ratio of greater than 100 per meter.
- 76. (new) The kit according to claim 28, wherein the solid support is a metal foil.
- 77. (new) The kit according to claim 76, wherein the metal foil has a thickness of less than 0.25 mm.